EXHIBIT M

PDR®

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PHYSICIANS' DESK REFERENCE®

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use of adverse eye findings in animal studies with drugs this class it is recommended that ophthalmic studies be ried out within a reasonable period of time after starting rapy and at periodic intervals thereafter if the drug is to used for an extended period of time.

formation for Patients:
aution should be exercised by patients whose activities quire alertness if they experience drowsiness, dizziness, rtigo or depression during therapy with the drug.

Drug Interactions:
In vitro studies have shown that naproxen anion, because of affinity for protein, may displace from their binding sites other drugs which are also albumin-bound. Theoretically, the naproxen anion itself could likewise be displaced. Short-rm controlled studies failed to show that taking the drug nificantly affects prothrombin times when administered individuals on coumarin-type anticoagulants. Caution is vised nonetheless, since interactions have been seen with ther nonsteroidal agents of this class. Similarly, patients ceiving the drug and a hydantoin, sulfonamide or sulfonyl-rea should be observed for signs of toxicity to these drugs.
he natriuretic effect of furosemide has been reported to be hibited by some drugs of this class. Inhibition of renal lith-m clearance leading to increases in plasma lithium concen-rations has also been reported.
his and other nonsteroidal anti-inflammatory drugs can duce the antihypertensive effect of propranolol and other eta-blockers.
robenecid given concurrently increases naproxen anion asma levels and extends its plasma half-life significantly. aution should be used if this drug is administered concomi-antly with methotrexate. Naproxen and other nonsteroidal nti-inflammatory drugs have been reported to reduce the ubular secretion of methotrexate in an animal model, possi-ly enhancing the toxicity of that drug.

Drug/Laboratory Test Interactions:
he drug may decrease platelet aggregation and prolong leeding time. This effect should be kept in mind when bleed-ng times are determined.
he administration of the drug may result in increased uri-ary values for 17-ketogenic steroids because of an interac-ion between the drug and/or its metabolites with m-dinitro-enzene used in this assay. Although 17-hydroxy-corticoster-id measurements (Porter-Silber test) do not appear to be rtifactually altered, it is suggested that therapy with the rug be temporarily discontinued 72 hours before adrenal nction tests are performed.
he drug may interfere with some urinary assays of 5-ydroxy indoleacetic acid (5HIAA).

Carcinogenesis:
A two-year study was performed in rats to evaluate the carci-nogenic potential of the drug. No evidence of carcinogenicity as found.

Pregnancy:
Teratogenic Effects: Pregnancy Category B. Reproduction tudies have been performed in rats, rabbits and mice at oses up to six times the human dose and have revealed no vidence of impaired fertility or harm to the fetus due to the rug. There are, however, no adequate and well-controlled tudies in pregnant women. Because animal reproduction tudies are not always predictive of human response, the rug should not be used during pregnancy unless clearly eeded. Because of the known effect of drugs of this class on he human fetal cardiovascular system (closure of ductus rteriosus), use during late pregnancy should be avoided.
Non-teratogenic Effects: As with other drugs known to nhibit prostaglandin synthesis, an increased incidence of ystocia and delayed parturition occurred in rats.

Nursing Mothers:
he naproxen anion has been found in the milk of lactating omen at a concentration of approximately 1% of that found n the plasma. Because of the possible adverse effects of pros-aglandin-inhibiting drugs on neonates, use in nursing moth-rs should be avoided.

Pediatric Use:
Pediatric indications and dosage recommendations have not been established for NAPROSYN® (naproxen).

ADVERSE REACTIONS
Adverse reactions reported in controlled clinical trials in 960 patients treated for rheumatoid arthritis or osteoarthritis are listed below. In general, these reactions were reported 2 to 10 times more frequently than they were in studies in the 862 patients treated for mild to moderate pain or for dysmenorrhea.

Incidence greater than 1%
Gastrointestinal: The most frequent complaints reported related to the gastrointestinal tract. They were: constipation*, heartburn*, abdominal pain*, nausea*, dyspepsia, diarrhea, stomatitis.
Central Nervous System: Headache*, dizziness*, drowsiness*, lightheadedness, vertigo.
Dermatologic: Itching (pruritus)*, skin eruptions*, ecchymoses*, sweating, purpura.
Special Senses: Tinnitus*, hearing disturbances, visual disturbances.
Cardiovascular: Edema*, dyspnea*, palpitations.
General: Thirst.
* Incidence of reported reactions between 3% and 9%. Those reactions occurring in less than 3% of the patients are unmarked.

Incidence less than 1%
Probable Causal Relationship:
The following adverse reactions were reported less frequently than 1% during controlled clinical trials and through voluntary reports since marketing. The probability of a causal relationship exists between the drug and these adverse reactions:
Gastrointestinal: Abnormal liver function tests, gastrointestinal bleeding and/or perforation, hematemesis, jaundice, melena, peptic ulceration with bleeding and/or perforation, vomiting.
Renal: Glomerular nephritis, hematuria, interstitial nephritis, nephrotic syndrome, renal disease.
Hematologic: Eosinophilia, granulocytopenia, leukopenia, thrombocytopenia.
Central Nervous System: Depression, dream abnormalities, inability to concentrate, insomnia, malaise, myalgia and muscle weakness.
Dermatologic: Alopecia, photosensitive dermatitis, skin rashes.
Special Senses: Hearing impairment.
Cardiovascular: Congestive heart failure.
Respiratory: Eosinophilic pneumonitis.
General: Anaphylactoid reactions, menstrual disorders, pyrexia (chills and fever).
Causal Relationship Unknown:
Other reactions have been reported in circumstances in which a causal relationship could not be established. However, in these rarely reported events, the possibility cannot be excluded. Therefore these observations are being listed to serve as alerting information to the physicians:
Hematologic: Agranulocytosis, aplastic anemia, hemolytic anemia.
Central Nervous System: Cognitive dysfunction.
Dermatologic: Epidermal necrolysis, erythema multiforme, Stevens-Johnson syndrome, urticaria.
Gastrointestinal: Ulcerative stomatitis.
Cardiovascular: Vasculitis.
General: Angioneurotic edema, hyperglycemia, hypoglycemia.

OVERDOSAGE
Significant overdosage may be characterized by drowsiness, heartburn, indigestion, nausea or vomiting. No evidence of toxicity or late sequelae have been reported 5 to 15 months after ingestion for three to seven days of doses up to 3,000 mg of naproxen. One patient ingested a single dose of 25 g of naproxen and experienced mild nausea and indigestion. It is not known what dose of the drug would be life threatening. The oral LD_{50} of the drug is 543 mg/kg in rats, 1234 mg/kg in mice, 4110 mg/kg in hamsters and greater than 1000 mg/kg in dogs.
Should a patient ingest a large number of tablets, accidentally or purposefully, the stomach may be emptied and usual supportive measures employed. Animal studies suggest that the prompt administration of 5 grams of activated charcoal would tend to reduce markedly the absorption of the drug. It is not known if the drug is dialyzable.

DOSAGE AND ADMINISTRATION
For Rheumatoid Arthritis, Osteoarthritis, and Ankylosing Spondylitis:
The recommended starting dose in adults is one 250 mg tablet or one 375 mg tablet twice daily (morning and evening). During long-term administration, the dose may be adjusted up or down depending on the clinical response of the patient. A lower daily dose may suffice for long-term administration. Daily doses higher than 1000 mg in these indications have not been studied. The morning and evening doses do not have to be equal in size and the administration of the drug more frequently than twice daily is not necessary. Symptomatic improvement in arthritis usually begins within two weeks. However, if improvement is not seen within this period, a trial for an additional two weeks should be considered.
For Acute Gout:
The recommended starting dose is 750 mg, followed by 250 mg every eight hours until the attack has subsided.
For Mild to Moderate Pain, Primary Dysmenorrhea and Acute Tendinitis and Bursitis:
The recommended starting dose is 500 mg, followed by 250 mg every 6 to 8 hours, as required. The total daily dose should not exceed 1,250 mg.

HOW SUPPLIED
NAPROSYN (naproxen) is available in scored tablets of 250 mg (yellow) in bottles of 100 tablets (NDC 18393-272-42) (NSN 6505-01-026-9730) and 500 tablets (NDC 18393-272-62) (NSN 6505-01-046-0126) or in cartons of 100 individually blister packed tablets (NDC 18393-272-53) (NSN 6505-01-097-9611) and in 375 mg (peach) tablets in bottles of 100 tablets (NDC 18393-273-42) (NSN 6505-01-135-8462) and 500 tablets (NDC 18393-273-62) (NSN 6505-01-204-5297) or in cartons of 100 individually blister packed tablets (NDC 18393-273-53) (NSN 6505-01-204-5298). The 500 mg (yellow) tablets are available in bottles of 100 tablets (NDC 18393-277-42) (NSN 6505-01-200-2474) and 500 tablets (NDC 18393-277-62). Store at room temperature in well-closed containers; dispense in light-resistant containers.
CAUTION: Federal law prohibits dispensing without prescription.
U.S. Patent Nos: 3,904,682; 3,998,966 and others.
 Revised 11/85
Shown in Product Identification Section, page 432

NASALIDE® ℞
[*na'zā-lide*]
(flunisolide)
Nasal Solution
0.025%
For Nasal Use Only

PRODUCT OVERVIEW
KEY FACTS
NASALIDE Nasal Solution, intended for administration as a spray to the nasal mucosa, contains the active ingredient flunisolide, an anti-inflammatory topical steroid. Clinical studies with flunisolide have shown local therapeutic activity on nasal mucous membranes, including reduction of symptoms of stuffy nose, runny nose and sneezing, with minimal evidence of systemic activity at the recommended doses.

MAJOR USES
NASALIDE is indicated for the topical treatment of the symptoms of seasonal or perennial rhinitis when effectiveness of or tolerance to conventional treatment is unsatisfactory. Symptomatic relief is usually seen within a few days after starting NASALIDE, but may not occur in some patients for as long as two weeks.

SAFETY INFORMATION
See complete safety information set forth below.

PRESCRIBING INFORMATION
NASALIDE® ℞
[*na'zā-lide*]
(flunisolide)
Nasal Solution
0.025%
For Nasal Use Only

A product of Syntex Laboratories, Inc.

DESCRIPTION
NASALIDE® (flunisolide) nasal solution is intended for administration as a spray to the nasal mucosa. Flunisolide, the active component of NASALIDE nasal solution, is an anti-inflammatory steroid with the chemical name: 6α-fluoro-11β, 16α, 17,21-tetrahydroxypregna-1,4- diene-3,20-dione cyclic 16,17-acetal with acetone (USAN).
Flunisolide is a white to creamy white crystalline powder with a molecular weight of 434.49. It is soluble in acetone, sparingly soluble in chloroform, slightly soluble in methanol, and practically insoluble in water. It has a melting point of about 245°C.
Each 25 ml spray bottle contains flunisolide 6.25 mg (0.25 mg/ml) in a solution of propylene glycol, polyethylene glycol 3350, citric acid, sodium citrate, butylated hydroxyanisole, edetate disodium, benzalkonium chloride, and purified water, with NaOH and/or HCl added to adjust the pH to approximately 5.3. It contains no fluorocarbons.
After priming the delivery system for NASALIDE, each actuation of the unit delivers a metered droplet spray containing approximately 25 mcg of flunisolide. The size of the droplets produced by the unit is in excess of 8 microns to facilitate deposition on the nasal mucosa. The contents of one nasal spray bottle deliver at least 200 sprays.

CLINICAL PHARMACOLOGY
NASALIDE® (flunisolide) has demonstrated potent glucocorticoid and weak mineralocorticoid activity in classical animal test systems. As a glucocorticoid it is several hundred times more potent than the cortisol standard. Clinical studies with flunisolide have shown therapeutic activity on nasal mucous membranes with minimal evidence of systemic activity at the recommended doses.
A study in approximately 100 patients which compared the recommended dose of flunisolide nasal solution with an oral dose providing equivalent systemic amounts of flunisolide has shown that the clinical effectiveness of NASALIDE, whenused topically as recommended, is due to its direct local effect and not to an indirect effect through systemic absorption.
Following administration of flunisolide to man, approximately half of the administered dose is recovered in the urine and half in the stool; 65–70% of the dose recovered in urine is the primary metabolite, which has undergone loss of

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